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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,352

09/30/2003

Lee Johnson

NC 84,495

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26384 7590 03/22/2007  
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/673,352

Applicant(s)

JOHNSON ET AL.

Examiner

Nathan A. Bowers

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 1) Claims 24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe an embodiment in which only a single cathode or a single anode used. The entirety of the written description and drawings point only to examples in which a plurality of cathodes and a plurality of anodes are utilized. The term stimulator *array* in the specification and claims implies the use of many anodes and many cathodes arranged in a pattern.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2) Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 includes contradictory language that makes the nature of the claimed anode and cathode arrangement unclear. Lines 10-13 state that the at least one anode comprises only a

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single anode, but then later state that the at least one anode comprises more than one anode. The same is language is used when describing the cathodes. Accordingly, it is uncertain whether a plurality of anodes/cathodes or a singular anode/cathode is claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3) Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Hoff (US 20050054969).

Hoff discloses a device for electroporating cultured cells. Paragraph [0022] states that a fluid flow chamber is used to deliver samples to a stimulator array and conducting electrode materials. The stimulator array is in communication with electrodes (Figure 1:14 and Figure 1:15) that are capable of applying spatially variant voltages for electroporation. Paragraph [0020] states that the stimulator array comprises at least one anode and at least one cathode, and is structured for connection with a voltage source. This is additionally described in paragraphs [0018]-[0021], [0036]-[0038] and [0043]. Hoff specifically teaches that the electrode materials form anodes and cathodes that cause electroporation when a voltage is applied.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 4) Claims 21 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff (US 20050054969) in view of Nicoletis (US 20060206161) and/or Dzekunov (US 20040197883).

With respect to claim 21, Hoff discloses the apparatus as previously described above. As stated, it is believed that Hoff discloses a stimulator array in communication with the conducting electrode materials. However, if Hoff's base (12) and associated voltage and current source cannot be considered a stimulator array, then Hoff fails to anticipate the claim.

Nicolelis discloses a high-density multichannel microwire electrode array for measuring cell response to electrical signals. Paragraphs [0056]-[0077] state that microwire arrays are implanted upon a computer controlled printed circuit board capable of receiving information derived from each individual electrode.

Hoff and Nicolelis are analogous art because they are from the same field of endeavor regarding electrical manipulation devices for cells.

At the time of the invention, it would have been obvious to position the electrodes disclosed by Hoff upon a printed circuit board chip controllable by a computer. Nicolelis teaches that this arrangement is beneficial because it allows one to construct a high-density electrode array capable of interacting with a substantial number of cells simultaneously. Hoff already teaches that it is known to apply a time varying voltage of independent electrode clusters to induce electroporation. It would have been obvious to utilize a circuit board to accomplish this task because circuit board materials are inexpensive, easily machined, and capable of facilitating high densities of implanted electrodes.

With respect to claim 23, Hoff discloses the apparatus as previously described above. As stated, it is believed that Hoff discloses a fluid flow chamber in communication with the

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stimulator array and electrodes. However, it is admitted that Hoff's offers only a limited description of the proposed fluid flow chamber in paragraph [0022].

Dzekunov discloses an electroporation device that comprises a fluid flow chamber through which cell samples are allowed to move. The chamber comprises electrodes that apply voltages sufficient to porate the cells as they flow through the chamber. The chamber includes inflow and outflow ports, valves, tubing, and a pump. This is described in Figure 12 and paragraphs [0191]-[0193] and [0240]-[0242].

Hoff and Dzekunov are analogous art because they are from the same field of endeavor regarding electroporation apparatuses.

At the time of the invention, it would have been obvious to ensure that the electroporation system proposed by Hoff is provided with a substantial fluid flow chamber that comprises access ports, valves, and a pump. Dzekunov teaches that flow cells are beneficial because they can be used to automatically porate and treat a large number of cells in a short amount of time. The use of an automatic flow cell system is desirable because it can be easily and inexpensively operated when compared to other electroporation systems.

With respect to claims 24-27, Hoff and Nicolelis/Dzekunov disclose the apparatus set forth in claim 21 as set forth in the 35 U.S.C. 103 rejections above. In addition, Hoff indicates in the Figures that a plurality of anodes and cathodes are arranged in alternating fashion. Each cathode is surrounded by many of anodes. Generally, the duplication and rearrangement of parts is not sufficient to overcome the prior art. See MPEP 2144.04. In this case, varying the number and positioning of the anodes and cathodes is not considered to be a patentable difference.

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5) Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff (US 20050054969) in view of Nicolelis (US 20060206161) and/or Dzekunov (US 20040197883) as applied to claim 21, and further in view of Merritt (US 20040241965).

Hoff and Nicolelis/Dzekunov disclose the apparatus set forth in claim 21 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the electrode material comprises glass hybridized to the simulator array with indium bumps.

Merritt discloses a high aspect ratio microelectrode array useful in the delivery and detection of electrical signals at discrete, spatially resolved locations. Paragraph [0037] indicates that it is known in the art to utilize indium bumps to make electrical connections between two arrays of electrical contacts.

Hoff, Nicolelis, Dzekunov and Merritt are analogous art because they are from the same field of endeavor regarding electrical manipulation devices.

At the time of the invention, it would have been obvious to connect the microwire glass electrodes to the simulator array using the well known process of indium bump bonding. Merritt teaches in paragraph [0037] that wire electrodes easily can be pushed into indium in order to create an electrical connection between an array of electronic unit cells and an array of microelectrodes.

### ***Response to Arguments***

In response to Applicant's amendments, all previously made rejections under 35 U.S.C. 112 in the prior Office Action (10/31/06) have been withdrawn. Please consider the newly made rejections under 35 U.S.C. 112.



Applicant's arguments filed 18 January 2007 with regard to the 35 U.S.C. 102 and 35 U.S.C. 103 rejections involving Hoff have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) Hoff fails to disclose a conducting portion having a second side being disposed to receive a layer of a plurality of objects that are to have a substance disposed therein through electroporation. On the contrary, Hoff discloses that electrodes 14 and 15 are in direct contact with the target tissue.*

In response to Applicant's arguments, please consider the following comments.

The array of electrodes 14 and 15 disclosed by Hoff are considered to be conducting portions having first sides and second sides. As required by the claim, these electrodes are clearly in electrical contact with cells on one side. The electrodes are also in electrical contact with microwires 16 carrying anodic and cathodic signals on their other side. It is not understood why Applicant does not consider the electrodes of Hoff to be legitimate "conducting portions" because the electrodes are in direct contact with the cells. Applicant describes on pages 6 and 7 of the specification and in Figures 1 and 2 that the instant invention utilizes electrodes that are in direct contact with cells.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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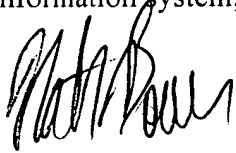
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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